



SYSMEX x QIAGEN

Your CDx team just got better

**Two world-class companies
have combined efforts to
accelerate global CDx access**

Your CDx team members

Sysmex Inostics:

- Developers of one of the most sensitive NGS liquid biopsy tests on market
- Plasma-Safe-SeqS (PSS) designed to leave no molecule behind
- 10 years of CLIA lab support for breakthroughs in clinical trials
- Creators of first commercially available liquid biopsy test, OncoBEAM™

QIAGEN:

- Unparalleled global CDx development and commercialization capabilities
- Over 15 years of developing CDx product with pharmaceutical partners
- Strong regulatory capabilities with ten CDx FDA PMA approvals
- Capabilities to register CDx assays globally in all target markets

How to work with us

Contact us

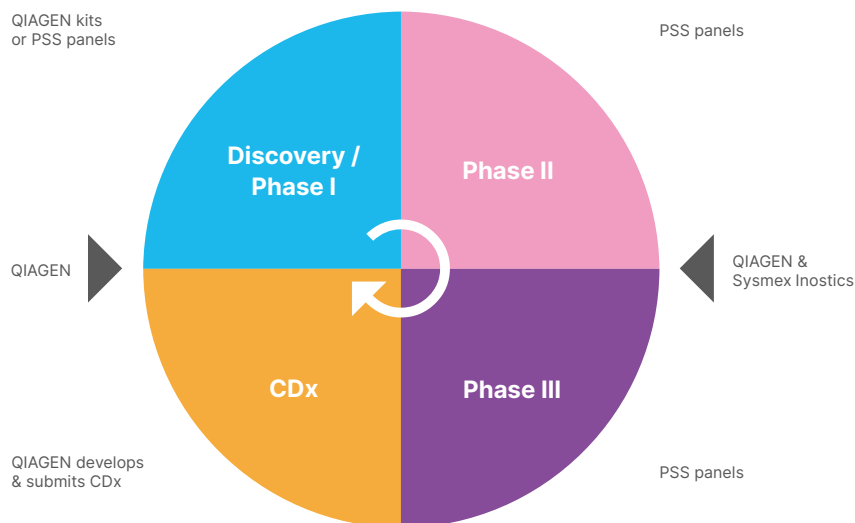
- Scan the QR code on the back of this brochure or visit <https://sysmex-inostics.com/asco-2022> to fill out the contact form and get more information.

Meet with us

- Virtually, in-person or hybrid
- Our team (QIAGEN & Sysmex Inostics) will engage with yours from the beginning to gather your CDx needs. This will help us strategize and verify technology needs, and timelines are a good fit to move forward.

Clinical trial journey

Our combined areas of expertise allow us to anticipate and understand your various needs throughout the clinical trial process.



On-market CLIA-validated PSS panels

PSS PANELS	CLINICALLY RELEVANT GENE REGIONS	CLINICAL INTENDED USES	LIMIT OF DETECTION (95% CI)	DNA INPUT LEVELS TESTED	CORRESPONDING MAF FOR 20,000 COPIES (~66 NG DNA)
RAS-RAF-SEQ RAS-RAF pathway	BRAF, KRAS, NRAS, AKT1, PIK3CA	<ul style="list-style-type: none"> Therapy selection Therapeutic monitoring 	7 mutant molecules	1,000–20,000 GE	0.035% MAF
HPV-SEQ HPV-related cancers	HPV 16, HPV 18	<ul style="list-style-type: none"> Therapy selection Therapeutic monitoring Recurrence surveillance 	5 HPV 16/18 molecules	1,000–30,000 GE	0.025% AF
BC-SEQ Breast cancer	AKT1, ERBB2, ESR1, KRAS, PIK3CA, TP53	<ul style="list-style-type: none"> Therapy selection Therapeutic monitoring Recurrence surveillance 	6 mutant molecules	1,000–20,000 GE	0.030% MAF
AML-MRD-SEQ AML MRD	FLT3, IDH1, IDH2, NPM1, BCOR, BRAF, CEBPA, GATA2, JAK2, KIT, KRAS, NRAS, PRPF8, PTPN11, SETBP1, SF3B1, SRSF2, TP53, U2AF1, ZRSR2	<ul style="list-style-type: none"> Therapy selection Therapeutic monitoring MRD detection Recurrence surveillance 	7 mutant molecules	2,000–20,000 GE	0.035% MAF
HNSCC-SEQ H&N HPV(-) cancers	CDKN2A, EGFR, ERBB2, FGFR3, HRAS, KRAS, NOTCH1, PIKCA, PTEN, TP53	<ul style="list-style-type: none"> Therapy selection Therapeutic monitoring Recurrence surveillance 	8 mutant molecules	1,000–20,000 GE	0.04% MAF

- High specificity observed for all configurations: Vast majority of base positions exhibit background noise < 1 MM
- High detection rates and low noise are observed across a range of DNA inputs

PSS technology platform, general test specifications

	CELL-FREE DNA ANALYSIS FOR SOLID TUMORS AND HPV	HEMATOLOGICAL MALIGNANCIES
Sample types accepted	<ul style="list-style-type: none"> Whole blood Frozen plasma Purified cfDNA 	<ul style="list-style-type: none"> Whole blood Purified cells (isolated from blood) Purified DNA
Sample requirements	<ul style="list-style-type: none"> 2×10mL blood collection tubes required, additional tube may be recommended for certain studies Sysmex Inostics' specimen collection and shipping kits include Streck blood collection tubes Plasma or purified cfDNA from samples collected in Streck or EDTA tubes is accepted 	<ul style="list-style-type: none"> ~5 × 10⁶ cells recommended ~10 mL plasma for cfDNA analysis
Turnaround time	7 – 10 business days	

**Learn how QIAGEN & Sysmex Inostics
are accelerating CDx development**

